

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

JANSSEN PHARMACEUTICALS, INC.
and JANSSEN PHARMACEUTICA NV,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA,
INC.,

Defendant.

Civil Action No. 2:18-00734
(CCC)(LDW)

JANSSEN PHARMACEUTICALS, INC.
and JANSSEN PHARMACEUTICA NV,

Plaintiffs,

v.

MYLAN LABORATORIES LIMITED,

Defendant.

Civil Action No. 2:19-16484
(CCC)(LDW)

PLAINTIFFS' NOTICE OF SUPPLEMENTAL AUTHORITY

Plaintiffs Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV (“Janssen”) file this Notice to call the Court’s attention to the attached decision of the U.S. Court of Appeals for the Federal Circuit in *Natera, Inc. v. NeoGenomics Lab’ys, Inc.*, Case No. 2024-1324, 2024-1409 (July 12, 2024). The decision is

relevant to the remand proceedings, in particular to Teva's and Mylan's argument that the Federal Circuit's decision requires this Court to disregard unclaimed factors (*e.g.*, safety and rapid efficacy) in assessing obviousness. *See, e.g.*, D.I. 299 at 28-29, 42-43; D.I. 312 at 20-23, 53-54. *Natera*, a precedential opinion, confirms that unclaimed factors are relevant if a POSA would reasonably consider them:

Unclaimed factors relevant to the feasibility of creating a useful claimed invention can impact the motivation to combine analysis if a skilled artisan would reasonably consider them. *See Auris Health, Inc. v. Intuitive Surgical Operations, Inc.*, 32 F.4th 1154, 1159 (Fed. Cir. 2022) (considering evidence that combination of elements would come at the expense of precision required for surgery as relevant to motivation to combine, even though claims did not require precision). The district court was well within its discretion to consider whether a skilled artisan would have reasonably expected to perform the claimed method with some level of precision.

For these reasons, we see no clear error in the district court's findings on motivation to combine or reasonable expectation of success.

Natera, slip op. at 11-12.

Natera is entirely consistent with the Federal Circuit's remand instructions. The Federal Circuit instructed this Court to reassess obviousness in light of its instructions regarding the scope of the claims. But the Federal Circuit did *not* prohibit this Court on remand from considering all unclaimed factors that a POSA would reasonably consider when finding new facts as to motivation to modify and

reasonable expectation of success. To the contrary, the Federal Circuit recognized that unclaimed factors could be relevant to a POSA working to develop a paliperidone palmitate dosing regimen. *See, e.g., Janssen Pharms., Inc. v. Teva Pharms. USA, Inc.*, 97 F.4th 915, 928 (Fed. Cir. 2024) (“Whatever role safety and efficacy data may play in assessing the strength of a motivation or a lack of motivation to combine”); *id.* at 929 (“we recognize that obtaining specific results or outcomes in a population of patients could have been one motivation for modifying the protocol”). *Natera* confirms that in instructing this Court on the controlling law, the Federal Circuit did not mean to suggest that the Court should disregard evidence of unclaimed factors such as a POSA’s expectations of safety and rapid efficacy.

Dated: July 16, 2024

/s/ Keith J. Miller

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